

From: MS Outlook::Anastassios D. Retzios, Ph.D.

To:

Petrone, Michael at Roberts Pharmaceutical Corporation;
MS Outlook::Alvin Howard (E-mail)

cc:

MS Outlook::Frank J. Sasinowski (E-mail);
MS Outlook::Casamento, Charles

Subject: Emitasol Clinical Development

Date: 10:24 AM

Dear Michael,

I have forwarded all pertinent material to Mr. Frank Sasinowski, including the latest one by GloboMax. Hopefully, we will resolve this shortly and we will proceed.

Reading the GloboMax reply that you included in your latest e-mail, I have the following remarks:

Regarding the "global analysis", their position is:

[Globomax: This recommendation still stands. However in response to the Ribogene comment related to the FDA meeting minutes, we would like to point out that the comment quoted by Ribogene was not related to the current study design or a random withdrawal design, but to the active control, equivalence study. Therefore, it is unclear if this statement can be equally applied to the current study design. In the recent FDA letter, the only statement relating to this point was that a global assessment be included as a **secondary endpoint** (my emphasis).]

- a. This is not how GloboMax felt during the meeting when David Young himself stated that this particular comment by the FDA was highly pertinent (and this is why the meeting had the final recommendation that it had)
- b. The word "endpoint" -never mind secondary- does not occur in the FDA letter. The FDA states: "a global assessment of therapy should be added to support the results of the SAQ". To me, this suggests an analysis, rather than additional questions to the subjects.
- c. The FDA is still under the impression that "gastric emptying" is our **secondary endpoint**. We have not notified them as yet that we wish to remove this and perform it in an unspecified subset of subjects for information only.

For a quick resolution to this, at the end of the letter we are invited to ask questions for clarification. Would Alvin be willing to contact the reviewer to clarify Point 2 and provide us with a copy of the discussion transcript? Can he authorize anyone else to do this? This seems to be the expeditious thing to do and it will end all uncertainty.

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